

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Jeffrey L. SOUTHARD et al.

Application No.: 10/586,209

International Filing Date: January 13, 2005

For: CONTROLLED RELEASE CGRP  
DELIVERY COMPOSITION FOR  
CARDIOVASCULAR AND RENAL  
INDICATIONS

Examiner: R. Li

Group Art Unit: 1646

Confirmation No.: 2819

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & § 1.98**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

Applicants would like to draw the Examiner's attention to the fact that item no. 11 (WO 90/03768) listed on the attached Form PTO/SB/08a/b is the English language counterpart of item no. 2 (JP 4-503163).

Applicants would like to draw the Examiner's attention to the fact that item no. 39 (EP 0 467 389) listed on the Form PTO/SB/08a/b filed November 17, 2008 is the English language counterpart of item no. 3 (JP 5-103838).

Applicants would like to draw the Examiner's attention to the fact that item no. 1 (EP 0 539 751) listed on the attached Form PTO/SB/08a/b is the English language counterpart of item no. 4 (JP 5-305135).

Applicants would like to draw the Examiner's attention to the fact that item no. 12 (WO 95/27481) listed on the attached Form PTO/SB/08a/b is the English language counterpart of item no. 6 (JP 9-511741).

Applicants would like to draw the Examiner's attention to the fact that item no. 14 (WO 99/38536) listed on the attached Form PTO/SB/08a/b is the English language counterpart of item no. 7 (JP 2002-501908).

Applicants would like to draw the Examiner's attention to the fact that item no. 13 (WO 99/18142) listed on the attached Form PTO/SB/08a/b is the English language counterpart of item no. 8 (JP 2002-516910).

Applicants would like to draw the Examiner's attention to the fact that item no. 15 (WO 00/24374) listed on the attached Form PTO/SB/08a/b is the English language counterpart of item no. 9 (JP 2002-528403).

Applicants would like to draw the Examiner's attention to the fact that item no. 16 (WO 02/098446) listed on the attached Form PTO/SB/08a/b is the English language counterpart of item no. 10 (JP 2003-104913).

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under 37 C.F.R. § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☒ A fee is required. ~~Accordingly, a Fee Transmittal Form (PTO/SB/17) is attached to this submission.~~
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the Issue Fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal Form (PTO/SB/17) is attached to this submission.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a

fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 560252000700.

Dated: January 21, 2011

Respectfully submitted,

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